UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,749	08/13/2002	Robert David Darrow	RD27658	8455

6147 7590 12/11/2008

GENERAL ELECTRIC COMPANY
GLOBAL RESEARCH
PATENT DOCKET RM. BLDG. K1-4A59
NISKAYUNA, NY 12309

EXAMINER	
LAMPRECHT, JOEL	

ART UNIT	PAPER NUMBER
3737	

NOTIFICATION DATE	DELIVERY MODE
12/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ldocket@crd.ge.com
rosssr@crd.ge.com
parkskl@crd.ge.com

Office Action Summary	Application No.	Applicant(s)	
	10/064,749	DARROW ET AL.	
	Examiner	Art Unit	
	JOEL M. LAMPRECHT	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-17 and 19-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-17, 19-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-17, 19-22, and 30-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *Claim 13 and the corresponding arguments of record with regard to claim 13 appear to claim that the processor responds to change in the position of a medical device by* ***repositioning*** *the medical device within a target region of interest with moving the subject*. A thorough and complete search of Applicant's specification has provided no such teaching or capability of the processor element. Independent claims 1, 23 and 32 are not included in this rejection as they do not explicitly recite that the processor system itself repositions the medical device, rather that the system (or method) provides feedback (or is for) to **assist(ing)** in repositioning (emphasis added).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-10, and 23-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumoulin et al. (U.S. Patent No. 5,251,635).

Regarding Claims 1, 7, and 23, Dumoulin et al. '635 teaches a medical device positioning system and method including a medical device adapted for internal use for performing the medical procedure, an imaging device (col. 1, lines 60-63), a medical device monitoring and positioning subsystem (col. 2, lines 2-10, 61-66, and 68) for monitoring the position of the medical device relative to a target region of interest within the subject and for providing feedback to an interface unit and responding to motion of at least one of the medical device or the subject in a predetermined fashion when the position of the medical device deviates from the target region of interest (col. 3, lines 1-4, 12-16 and 35-39), a tracking device, a processor coupled to the medical imaging device and the tracking device for generating images of the region of interest with a visual representation of the medical device superimposed on the images, where the processor is further adapted to monitor a position of the medical device relative to the region of interest and to respond to changes in the position and provide feedback to an interface and where the operator initiates image acquisition at a selected location through an interface which is adapted to respond to the operator's input (col. 4, lines 16-19 and col. 7, lines 24-43).

Regarding Claims 2, 4-6, Dumoulin et al. '635 teaches a monitoring subsystem that is adapted to receive configuration information that is tracking method information corresponding to the medical device (col. 3, lines 1-4 and 22-25), that has a

predetermined response of activating the imaging system to acquire a new image in response to the movement of the medical device relative to the target region within the subject, that provides advisory feedback to the interface unit when the medical device deviates from a target position (col. 4, lines 1 9-21, 25-35, 42-46 and 68), where the advisory feedback is a visual icon representing the position of the device (col. 5, line 1 and col. 7, lines 24-39).

Regarding Claims 8-10, and 26-29 Dumoulin et al. '635 teaches an imaging device that may be an MRI scanner, an X-ray device, a PET system, an ultrasound scanner or any other similar medical diagnostic imaging device, an invasive device that may be at least one of a biopsy needle guide, an invasive probe, an ablation device, a laparoscope and a therapeutic laser (col. 1, lines 60-63, col. 2, lines 25-28), an interface where the operator selects the desired position of the device and a coupling between the interface and the processor for displaying the images representing the region of interest and the medical device (col. 3, lines 1-4, col. 4, lines 22-48) where the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate the device to a region of interest (col. 7, lines 31-43 and 61-68 and col. 8, lines 1-3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 32 is rejected under 35 U.S.C. 102(b) as anticipated by Dumoulin et al. ('635) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dumoulin et al. ('635).

Regarding Claims 24, 25, and 32, Dumoulin et al. disclose all that is listed above, and also discloses advisory feedback when the medical device deviates from a target position in the form of updating the image on the monitor or interface visual output of the system including the icon of the device and the region of interest (Col 3 Line 25-Col 4 Line 50 and Col 7 Line 24-47). While this embodiment does not explicitly disclose providing a *text advisory*, the monitor is *capable of displaying text*. In the alternative, it would have been obvious to one skilled in the art to modify the advisory from *image feedback* as taught by Dumoulin et al. *to text feedba*ck as an alternative functional equivalent to produce feedback to the operator in lieu of constantly updated images

provides feedback to the user in a predetermined fashion that allows for the user to choose to terminate therapy, continue with therapy, move the device without moving the patient, or any other response that someone skilled in the art would reasonably provide.

Claims 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. '635, and further in view of Panescu et al. Dumoulin et al. '635 teaches all of the features of the present invention except that the monitoring subsystem receives configuration information about the device that is a model representation, where that information corresponds to a visual representation of the device for superimposing on the images acquired, and where the visual representation is a wire-frame model of the device.

In the same field of endeavor, Panescu et al. teaches a system for locating and positioning a catheter within a body where configuration information about the device is entered into the processing system (col. 6, lines 56-59). Panescu et al. also teaches that a graphical representation of the device may be provided and that the representation may be used in combination with the fluoroscopic images of the position of the device (col. 6, lines 31-46). Further, Panescu et al. teaches that a wire-frame image of the device may be used (col. 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the configuration input scheme and visual representations of Panescu et al. with the system of Dumoulin et al. in order to provide the operator with improved orientation of the

device within the subject (see for motivation Panescu et al. at col. 5, lines 65-67 and col. 6, lines 6-12).

Response to Arguments

Applicant's arguments filed 10/13/08 have been fully considered but they are not persuasive. Examiner has made clear that the specific wording of claim 13, does not include language such as “for repositioning” or “to assist repositioning”, rather cites that the processor responds to change "by repositioning the medical device within the target region of interest". The reason for this rejection is due to the fact that modern systems have the capacity to use a processor and according electromagnetic systems to actually move a medical device without any sort of physical intervention on the behalf of the operator or system outside the processor. Through the use of an electronic interface or input device with liquid crystal display, operators are able to use processing tools and electromagnetic systems to actually perform the operation of repositioning an element within an area of interest. The wording of claim 13 of the current application, when read in light of these advancements in technology, would be convoluted to one of ordinary skill in the art who could very reasonably read the claim to include the processor to be the element that is providing the repositioning of the object, rather than the operator or other method (guide-wire, biopsy needle handle, etc) which is apparently the intent of the instant application as argued by applicant in this response. This rejection is to alleviate any sort of confusion that might be a product of this sort of reasonable interpretation of the current wording of the claim. As is noted above, claim 1 is not included in this rejection for the simple fact that the processor is claimed as being "for

repositioning" rather than providing the function of "repositioning" as would be implied by the latter interpretation. The processor cannot reposition the device itself, it can only assist or be used "for repositioning" the device. Should applicant simply amend the claim to alleviate this issue and denote that the processor is "used for" or a "part of repositioning", then the previous rejection based on those merits would still apply.

Regarding the argument that Dumoulin does not disclose or suggest a medical device monitoring and positioning subsystem, Examiner respectfully disagrees and argues that the function of Dumoulin which acquires repeated images of a region of interest including the medical device itself, is sufficient to provide the capability to "monitor and reposition" a device by human hand and eye. Looking at a diagnostic image (feedback) which includes an instrument, a physician would of course be able to understand the anatomy and also understand if the device should be placed elsewhere.

Regarding the argument that Dumoulin '635 fails to disclose a text or audio advisory, Examiner has already stated above that Dumoulin provides AT LEAST a functional equivalent at least in the form of images (which under trained eye provide anatomical features allowing for an indicator of position of both the element itself and in relation to the anatomy). Additionally, none of the claims being argued *only* require a text or audio advisory. Claim 24 additionally lists a visual icon (as disclosed in Dumoulin), claim 25 additionally lists response of activating the device to acquire a new image, and claim 32 additionally includes repositioning the device within the region of interest without moving the subject.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Twiss et al. (U.S. Patent No. 5,375,596) maintains teachings of audio feedback from a device positioning system.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JML

/BRIAN CASLER/

Supervisory Patent Examiner, Art Unit 3737